



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-1465-N]

Medicare Program; Public Meetings in Calendar Year 2015 for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS) Coding and Payment Determinations

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the dates, time, and location of the Healthcare Common Procedure Coding System (HCPCS) public meetings to be held in calendar year 2015 to discuss our preliminary coding and payment determinations for all new public requests for revisions to the HCPCS. These meetings provide a forum for interested parties to make oral presentations or to submit written comments in response to preliminary coding and payment determinations. The discussion will be focused on responses to our specific preliminary recommendations and will include all items on the public meeting agenda. (Please note that two of CMS' 2015 HCPCS public meetings have a late starting time.)

DATES: Meeting Dates: The following are the 2015 HCPCS public meeting dates:

1. Thursday, May 7, 2015, **12 p.m. (noon)** to 5 p.m. eastern daylight time (e.d.t.)
(Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
2. Friday, May 8, 2015, 9 a.m. to 5 p.m. eastern daylight time (e.d.t.)
(Drugs/Biologicals/Radiopharmaceuticals/Radiologic Imaging Agents).
3. Thursday, May 21, 2015, **10 a.m.** to 5 p.m. eastern daylight time (e.d.t.)
(Supplies and Other).

4. Friday, May 22, 2015, 9 a.m. to 5 p.m. eastern daylight time (e.d.t.)

(Supplies and Other).

5. Wednesday, May 27, 2015, 9 a.m. to 5 p.m. e.d.t.

Durable Medical Equipment (DME) and Accessories; and Orthotics and Prosthetics (O&P).

Deadlines for Primary Speaker Registration and Presentation Materials: The deadline for registering to be a primary speaker and submitting materials and writings that will be used in support of an oral presentation are as follows:

- April 22, 2015 for the May 7, 2015 and May 8, 2015 public meetings.
- May 7, 2015 for the May 21, 2015 and May 22, 2015 public meetings.
- May 13, 2015 for the May 27, 2015 public meeting.

Registration Deadline for Attendees that are Foreign Nationals: Attendees that are foreign nationals (as described in section IV. of this notice) are required to identify themselves as such, and provide the necessary information for security clearance (as described in section IV. of this notice) to the public meeting coordinator at least 12 business days in advance of the date of the public meeting the individual plans to attend. Therefore, the registration deadlines for attendees that are foreign nationals are as follows:

- April 20, 2015 for the May 7, 2015 and May 8, 2015 public meetings.
- May 5, 2015 for the May 21, 2015 and May 22, 2015 public meetings.
- May 11, 2015 for the May 27, 2015 public meeting.

Registration Deadlines for all Other Attendees: All individuals who are not foreign nationals who plan to enter the building to attend the public meeting must register for each date that they plan on attending. The registration deadlines are different for each meeting. Registration deadlines are as follows:

- April 30, 2015 for the May 7, 2015 and May 8, 2015 public meetings.

- May 14, 2015 for the May 21, 2015 and May 22, 2015 public meeting dates.
- May 20, 2015 for the May 27, 2015 public meeting date.

Deadlines for Requesting Special Accommodations: Individuals who plan to attend the public meetings and require sign-language interpretation or other special assistance must request these services by the following deadlines:

- April 23, 2015 for the May 7, 2015 and May 8, 2015 public meetings.
- May 7, 2015 for the May 21, 2015 and May 22, 2015 public meetings.
- May 13, 2015 for the May 27, 2015 public meeting.

Deadline for Submission of Written Comments: Written comments and other documentation in response to a preliminary coding or payment determination that are received by no later than the date of the public meeting at which the code request is scheduled for discussion, will be considered in formulating a final coding decision.

ADDRESSES: Meeting Location: The public meetings will be held in the main auditorium of the central building of the Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Submission of Written Comments: Written comments may either be e-mailed to HCPCS@cms.hhs.gov or sent via regular mail to Jennifer Carver, HCPCS Public Meeting Coordinator, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5-08-27, Baltimore, MD 21244-1850.

Registration and Special Accommodations: Individuals wishing to participate or who need special accommodations or both must register by completing the on-line registration located at www.cms.hhs.gov/medhcpcsgeninfo or by contacting Jennifer Carver at (410)786-6610 or Jennifer.Carver@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT:

Jennifer Carver at (410)786-6610 or Jennifer.Carver@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554). Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new durable medical equipment (DME) under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice for new DME are in response to the mandate of section 531(b) of BIPA.

In the November 23, 2001 **Federal Register** (66 FR 58743), we published a notice providing information regarding the establishment of the public meeting process for DME. It is our intent to distribute any materials submitted to CMS to the Healthcare Common Procedure Coding System (HCPCS) workgroup members for their consideration. CMS and the HCPCS workgroup members require sufficient preparation time to review all relevant materials. Therefore, we are implementing a 10-page submission limit and firm deadlines for receipt of any presentation materials a meeting speaker wishes us to consider. For this reason, our HCPCS Public Meeting Coordinator will only accept and review presentation materials received by the deadline for each public meeting, as specified in the **DATES** section of this notice.

The public meeting process provides an opportunity for the public to become aware of coding changes under consideration, as well as an opportunity for CMS to gather public input.

II. Meeting Registration

A. Required Information for Registration

The following information must be provided when registering:

- Name.

- Company name and address.
- Direct-dial telephone and fax numbers.
- E-mail address.
- Special needs information.

A CMS staff member will confirm your registration by e-mail.

B. Registration Process

1. Primary Speakers

Individuals must also indicate whether they are the "primary speaker" for an agenda item. Primary speakers must be designated by the entity that submitted the HCPCS coding request. When registering, primary speakers must provide a brief written statement regarding the nature of the information they intend to provide, and advise the HCPCS Public Meeting Coordinator regarding needs for audio/visual support. To avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence well in advance of the meeting. We will accept tapes and disk files that are received by the deadline for submissions for each public meeting as specified in the **DATES** section of this notice.

Please note CMS' page limit for primary speaker presentation materials. The sum of all presentation materials and additional supporting documentation may not exceed 10 pages (each side of a page counts as 1 page). An exception will be made to the 10-page limit only for relevant studies newly published between the application deadline and the public meeting date, in which case, we would like a copy of the complete publication as soon as possible. This exception applies only to the page limit and not the submission deadline.

The materials may be emailed or delivered by regular mail to the HCPCS Public Meeting Coordinator as specified in the **ADDRESSES** section of this notice. The materials must be

emailed or postmarked no later than the deadline specified in the **DATES** section of this notice.

Individuals will need to provide 35 copies if materials are delivered by mail.

2. “5-Minute Speakers”

To afford the same opportunity to all attendees, 5-minute speakers are not required to register as primary speakers. However, 5-minute speakers must still register as attendees by the deadline set forth under "Registration Deadlines for all Other Attendees" in the **DATES** section of this notice. Attendees can sign up only on the day of the meeting to do a 5-minute presentation. Individuals must provide their name, company name and address, contact information as specified on the sign-up sheet, and identify the specific agenda item that they will address.

C. Additional Meeting/Registration Information

Please note that two of CMS’ 2015 HCPCS public meetings have a late starting time as noted in the **DATES** section of this notice. Also, we were able this year to combine the Orthotics/Prosthetics and DME meeting into one public meeting date as noted in the **DATES** section of this notice.

The product category reported in the HCPCS code application by the applicant may not be the same as that assigned by us. Prior to registering to attend a public meeting, all participants are advised to review the public meeting agendas at www.cms.hhs.gov/medhcpcsgeninfo which identify our category determinations, and the dates each item will be discussed. Draft agendas, including a summary of each request and our preliminary decision will be posted on our HCPCS website at www.cms.hhs.gov/medhcpcsgeninfo at least 4 weeks before each meeting.

Additional details regarding the public meeting process for all new public requests for revisions to the HCPCS, along with information on how to register and guidelines for an effective presentation, will be posted at least 4 weeks before the first meeting date on the official

HCPCS website at www.cms.hhs.gov/medhpcsgeninfo. The document titled "Guidelines for Participation in Public Meetings for All New Public Requests for Revisions to the Healthcare Common Procedure Coding System (HCPCS)" will be made available on the HCPCS website at least 4 weeks before the first public meeting in 2015 for all new public requests for revisions to the HCPCS. Individuals who intend to provide a presentation at a public meeting need to familiarize themselves with the HCPCS website and the valuable information it provides to prospective registrants. The HCPCS website also contains a document titled "Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures," which is a description of the HCPCS coding process, including a detailed explanation of the procedures used to make coding determinations for all the products, supplies, and services that are coded in the HCPCS.

The HCPCS website also contains a document titled "HCPCS Decision Tree & Definitions" which illustrates, in flow diagram format, HCPCS coding standards as described in our Coding Procedures document.

A summary of each public meeting will be posted on the HCPCS website by the end of August 2015.

III. Presentations and Comment Format

We can only estimate the amount of meeting time that will be needed since it is difficult to anticipate the total number of speakers that will register for each meeting. Meeting participants should arrive early to allow time to clear security and sign-in. Each meeting is expected to begin promptly as scheduled. Meetings may end earlier than the stated ending time.

A. Oral Presentation Procedures

All primary speakers must register as provided under the section titled "Meeting Registration." Materials and writings that will be used in support of an oral presentation should be submitted to the HCPCS Public Meeting Coordinator.

The materials may be emailed or delivered by regular mail to the HCPCS Public Meeting Coordinator as specified in the **ADDRESSES** section of this notice. The materials must be emailed or postmarked no later than the deadline specified in the **DATES** section of this notice. Individuals will need to include 35 copies if materials are delivered by mail.

B. Primary Speaker Presentations

The individual or entity requesting revisions to the HCPCS coding system for a particular agenda item may designate one "primary speaker" to make a presentation for a maximum of 15 minutes. Fifteen minutes is the total time interval for the presentation, and the presentation must incorporate any demonstration, set-up, and distribution of material. In establishing the public meeting agenda, we may group multiple, related requests under the same agenda item. In that case, we will decide whether additional time will be allotted, and may opt to increase the amount of time allotted to the speaker by increments of less than 15 minutes.

Individuals designated to be the primary speaker must register to attend the meeting using the registration procedures described under the "Meeting Registration" section of this notice and contact one of the HCPCS Public Meeting Coordinators, specified in the **ADDRESSES** section. Primary speakers must also separately register as primary speakers by the date specified in the **DATES** section of this notice.

C. "5-Minute" Speaker Presentations

Meeting attendees can sign up at the meeting, on a first-come, first-served basis, to make presentations for up to 5 minutes on individual agenda items. Based on the number of items on the agenda and the progress of the meeting, a determination will be made at the meeting by the

meeting coordinator and the meeting moderator regarding how many “5-minute speakers” can be accommodated and/or whether the 5-minute time allocation would be reduced, to accommodate the number of speakers.

D. Speaker Declaration

On the day of the meeting, before the end of the meeting, all primary speakers and 5-minute speakers must provide a brief written summary of their comments and conclusions to the HCPCS Public Meeting Coordinator.

Every primary speaker and 5-minute speaker must declare at the beginning of their presentation at the meeting, as well as in their written summary, whether they have any financial involvement with the manufacturers or competitors of any items being discussed; this includes any payment, salary, remuneration, or benefit provided to that speaker by the manufacturer or the manufacturer's representatives.

E. Written Comments from Meeting Attendees

Written comments will be accepted from the general public and meeting registrants anytime up to the date of the public meeting at which a request is discussed. Comments must be sent to the address listed in the **ADDRESSES** section of this notice.

Meeting attendees may also submit their written comments at the meeting. Due to the close timing of the public meetings, subsequent workgroup reconsiderations, and final decisions, we are able to consider only those comments received in writing by the close of the public meeting at which the request is discussed.

IV. Security, Building, and Parking Guidelines

The meetings are held within the CMS Complex which is not open to the general public. Visitors to the complex are required to show a valid Government issued photo identification preferably a driver's license, at the time of entry. Participants will also be subject to a vehicle

security inspection before access to the complex is granted. Participants not in possession of a valid identification or who are in possession of prohibited items will be denied access to the complex. Prohibited items on federal property include but are not limited to, alcoholic beverages, illegal narcotics, explosives, firearms or other dangerous weapons (including pocket knives), dogs or other animals except service animals. Once cleared for entry to the complex participants will be directed to visitor parking by a security officer.

In order to ensure expedited entry into the building it is recommended that participants have their ID and a copy of their written meeting registration confirmation readily available and that they do not bring large/bulky items into the building. Participants are reminded that photography on the CMS complex is prohibited. CMS has also been declared a tobacco free campus and violators are subject to legal action. In planning arrival time, we recommend allowing additional time to clear security. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The invited guests may not enter the building earlier than 45 minutes before the convening of the meeting each day.

Guest access to the complex is limited to the meeting area, the main entrance lobby, and the cafeteria. If a visitor is found outside of those areas without proper escort they may be escorted off of the premises. Also be mindful that there will be an opportunity for everyone to speak and we request that everyone waits for the appropriate time to present their product or opinions. Disruptive behavior will not be tolerated and may result in removal from the meetings and escort from the complex. No visitor is allowed to attach USB cables, thumb drives or any other equipment to any CMS information technology (IT) system or hardware for any purpose at anytime. Additionally, CMS staff is prohibited from taking such actions on behalf of a visitor or utilizing any removable media provided by a visitor.

We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation. Special arrangements and approvals are required at least 2 weeks prior to each public meeting in order to bring pieces of equipment or medical devices. These arrangements need to be made with the public meeting coordinator. It is possible that certain requests made in advance of the public meeting could be denied because of unique safety, security or handling issues related to the equipment. A minimum of 2 weeks is required for approvals and security procedures. Any request not submitted at least 2 weeks in advance of the public meeting will be denied.

Foreign National Visitors are defined as Non-US Citizens, and non-lawful permanent residents, non-resident aliens or non-green-card holders.

Attendees that are foreign nationals must identify themselves as such, and provide the following information for security clearance to the public meeting coordinator by the date specified in the **DATES** section of this notice:

- Building to Visit/Destination.
- Visit start date, start time, end date, end time.
- Visitor full name.
- Gender.
- Visitor Title.
- Visitor Organization/Employer.
- Citizenship.
- Birth Place (City, Country).
- Date of Birth.
- ID Type (Passport or State Department ID).

- Passport issued by Country.
- ID (passport) Number.
- ID (passport) issue date.
- ID (passport) expiration date.
- Visa Type.
- Visa Number.
- Purpose of Visit.

Dated: February 18, 2015.

Marilyn Tavenner

Administrator,

Centers for Medicare & Medicaid Services.

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